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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/066,074

Applicant(s)

DAVIS, LLOYD MERVYN

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 05/02.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-16 in papers filed 18 March 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

3. The disclosure is objected to because of the following informalities: Page 8 of the specification is missing an Application number for the referenced co-pending application.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-16 are indefinite in Claim 1, step d) for the recitation “the at least two solutions” because the recitation lacks proper antecedent basis in the “at least one solution” recited in the claim. It is suggested that Claim 1 be amended to provide proper antecedent basis.

b. Claims 1-16 are indefinite in Claim 1, steps e) f) and i) for the recitations “the supported reagent” because the recitation lacks proper antecedent basis in the “at least one reagent molecule” recited in the claim. It is suggested that Claim 1 be amended to provide proper antecedent basis.

c. Claims 1-16 are indefinite in Claim 1, step e) for the recitation “ a solution comprising labeled molecules” because it is unclear whether the solution is the same solution as recited in step d. It is suggested that Claim 1 be amended to clarify.

d. Claim 8 is indefinite for the recitation “reactant labeled molecules” because the recitation lacks proper antecedent basis in Claim 4. It is suggested that Claim 8 be amended to provide proper antecedent basis.

e. Claim 13 is indefinite because the Markush group recites “or” twice. Therefore it is unclear which members constitute the Markush group.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 9-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Quake et al (U.S. Patent Application Publication No. 2002/0025529 A1 which is a divisional of 09/707,737 filed 6 November 2000).

Regarding Claim 1, Quake et al disclose a method for detecting labeled molecules that have participated in a chemical reaction the method comprising providing a flow cell, providing within the flow cell a solid support having a surface, supporting at least one reagent molecule to the surface (¶ 148) introducing at least two flowing solutions in to the flow cell wherein at least one solution comprises a labeled molecule and at least one solution comprises a buffer (¶ 177-178) wherein the two solutions are at different locations at any time i.e. the solution containing the label is introduced followed by the wash solution to remove unbound label (¶ 11 ¶ 178 and Claim 5) directing the flowing solutions with respect to the supported reagents to immerse the supported reagent in the solution comprising buffer, providing a light source and a detector, substantially simultaneously with step f) switching the detector (i.e. scan with the scanner) to cause the labeled molecule to pass through the illumination zone and detecting light emitted at the illumination zone (¶ 201-206).

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Regarding Claim 2, Quake et al disclose the method wherein a single labeled molecule is detected by the step of detecting light emitted from the illumination zone (§ 199).

Regarding Claim 3, Quake et al disclose the method wherein a chemical reaction is detected by detecting the presence of labeled molecules that have participated in the reaction i.e. labeled nucleotides (§ 178, 193 and 199).

Regarding Claim 4, Quake et al disclose the method wherein a single chemical reaction is detected by detecting the presence of a single labeled molecules (i.e. labeled nucleotide) that has participated in the reaction by detecting light emitted from the illumination zone (§ 178, 193, 199 and 218).

Regarding Claim 9, Quake et al disclose the method wherein the label is fluorescent (§ 181-182).

Regarding Claim 10, Quake et al disclose the method wherein the supported reagent comprises a supported nucleic acid and a polymerase and the solution of labeled molecules comprises at least one fluorescently labeled NTP with no quenching moiety (§ 178, 181 and 191).

Regarding Claim 11, Quake et al disclose the method wherein fluorescent labels are attached to the beta or gamma phosphate of the NTP i.e. pyrophosphate (containing the beta and gamma phosphates) is detected to detect NTP incorporation (§ 212).

Regarding Claim 12, Quake et al disclose the method wherein two or more distinguishable labels are used to label two or more different types of molecules i.e. a different label for each type of nucleotide (§ 181).

Regarding Claim 13, Quake et al disclose the method wherein optical detection includes identifying labels by their property e.g. excitation light, emission light, fluorescent lifetime and location of detection (§ 199 and 202-204).

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Regarding Claim 14, Quake et al disclose the method wherein an array of supported reagents (i.e. two-dimensional substrate with localized positions) and optical detections are separately accomplished for each reagent (§ 47, 132 and 204).

Regarding Claim 15, Quake et al disclose the method of claim 3 wherein a series of reactions is detected by repeating the method steps of Claim 1 (§ 9-11).

Regarding Claim 16, Quake et al disclose the method wherein the time interval between successive reaction is controlled by controlling time between successive repetitions (§ 223-229).

8. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams (U.S. Patent No. 6,255,083, filed 13 December 1999).

Regarding Claim 1, Williams discloses a method for detecting labeled molecules that have participated in a chemical reaction the method comprising providing a flow cell, providing within the flow cell a solid support having a surface, supporting at least one reagent molecule to the surface introducing at least two flowing solutions in to the flow cell wherein at least one solution comprises a labeled molecule and at least one solution comprises a buffer wherein the two solutions are at different locations at any time i.e. the solution containing the label is introduced followed by the wash solution to remove unbound label directing the flowing solutions with respect to the supported reagents to immerse the supported reagent in the solution comprising buffer, providing a light source and a detector, substantially simultaneously with step f) switching the detector (i.e. scan with the scanner) to cause the labeled molecule to pass through the illumination zone and detecting light emitted at the

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illumination zone (Column 2, line 17-Column 3, line 10 and Example 2, Column 14, line 61-Column 15, line 26).

Regarding Claim 2, Williams discloses the method wherein a single labeled molecule is detected by the step of detecting light emitted from the illumination zone (Example 2, Column 14, line 61-Column 15, line 26).

Regarding Claim 3, Williams discloses the method wherein a chemical reaction is detected by detecting the presence of labeled molecules that have participated in the reaction i.e. labeled nucleotides (Column 2, line 17-Column 3, line 10).

Regarding Claim 4, Williams discloses the method wherein a single chemical reaction is detected by detecting the presence of a single labeled molecules that has participated in the reaction by detecting light emitted from the illumination zone (Example 2, Column 14, line 61-Column 15, line 26).

Regarding Claims 5-8, Williams discloses the method wherein the concentration of the labeled molecules is above 10^{-5}M (Example 4, Column 17, lines 49-51).

Regarding Claim 9, Williams discloses the method wherein the label is fluorescent (Example 2, Column 15, lines 5-15).

Regarding Claim 10, Williams discloses the method wherein the supported reagent comprises a supported polymerase and a nucleic acid and the solution of labeled molecules comprises at least one fluorescently labeled NTP with no quenching moiety (Fig. 4, Column 13, lines 40-49 and Examples 1-2, Column 14, line 22-Column 15, line 15).

Regarding Claim 11, Williams discloses the method wherein fluorescent labels are attached to the gamma phosphate of the NTP (Column 2, lines 37-40).

Regarding Claim 12, Williams discloses the method wherein two or more distinguishable labels are used to label two or more different types of molecules i.e. a different label for each type of nucleotide (Column 2, lines 37-40 and Example 2, Column 14, line 62-Column 15, line 15).

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Regarding Claim 13, Williams discloses the method wherein optical detection includes identifying labels by their property e.g. excitation light, emission light and location of detection (Column 15, lines 5-15).

Regarding Claim 14, Williams discloses the method wherein an array of supported reagents and optical detections are separately accomplished for each reagent (Column 4, lines 47-50 and Column 15, lines 5-15).

Regarding Claim 15, Williams discloses the method of claim 3 wherein a series of reactions is detected by repeating the method steps of Claim 1 (Example 2, Column 14, line 62-Column 15, line 26).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al (U.S. Patent Application Publication No. 2002/0025529 A1 which is a divisional of 09/707,737 filed 6 November 2000) in view of Williams (U.S. Patent No. 6,255,083, filed 13 December 1999).

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Regarding Claims 5-8, Quake et al disclose a method for detecting labeled molecules that have participated in a chemical reaction the method comprising providing a flow cell, providing within the flow cell a solid support having a surface, supporting at least one reagent molecule to the surface (§ 148) introducing at least two flowing solutions in to the flow cell wherein at least one solution comprises a labeled molecule and at least one solution comprises a buffer (§ 177-178) wherein the two solutions are at different locations at any time i.e. the solution containing the label is introduced followed by the wash solution to remove unbound label (§ 11 § 178 and Claim 5) directing the flowing solutions with respect to the supported reagents to immerse the supported reagent in the solution comprising buffer, providing a light source and a detector, substantially simultaneously with step f) switching the detector (i.e. scan with the scanner) to cause the labeled molecule to pass through the illumination zone and detecting light emitted at the illumination zone (§ 201-206). Quake et al is silent regarding the concentration of the labeled molecules. However, labeled molecule concentrations above 10^{-5}M were well known and routinely practiced in the art at the time the claimed invention was made as taught by Williams (Example 4, Column 17, lines 43-58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the labeled molecule concentration of Quake et al to obtain concentrations above 10^{-5}M as instantly claimed. One of ordinary skill in the art would have been motivated to utilize routine experimentation to thereby derive the instantly claimed concentrations for the expected benefits of optimizing labeled molecule concentrations and maximizing experimental conditions.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

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Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-14 of U.S. Patent No. 10/059,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for detecting labeled molecules comprising the same method steps. The claims only differ in that the instant claims are drawn to the genus "labeled molecules" while the '754 claims are drawn to the species "labeled nucleotides".

The courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed method for detecting labeled molecules (i.e. genus) is obvious in view of the '754 method for detecting labeled nucleotides (i.e. species).

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Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 21, 2003